

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO. 053466-0365

Applicant: Hiroaki ITO et al.

Title: A PREVENTIVE OR THERAPEUTIC AGENT FOR
INFLAMMATORY BOWEL DISEASE COMPRISING IL-6
ANTAGONIST AS AN ACTIVE INGREDIENT

Appl. No.: Unassigned

Filing Date: 10/03/2003

Examiner: Unassigned

Art Unit: 1646

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop PATENT APPLICATION
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/646,188 filed on September 14, 2000. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

Appl. No. Unassigned

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b),
within three (3) months of the filing date of the application.

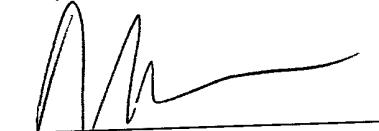
RELEVANCE OF EACH DOCUMENT

The relevance of the documents is explained in the parent application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,



Harold C. Wegner
Attorney for Applicant
Registration No. 25,258

October 3, 2003
Date

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: October 3, 2003

(use as many sheets as necessary)

Sheet

1 of 2

Complete if Known

Application Number	Unassigned
Filing Date	10/03/2003
First Named Inventor	Hiroaki ITO et al.
Group Art Unit	1646
Examiner Name	Unassigned
Attorney Docket Number	053466-0365

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENT							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Office ³	Number ⁴				
	A1	WO	96/40966	A1	Private Biologicals Corporation	12/19/1996	
	A2	JP	7-324097			12/12/1995	
	A3	JP	8-311098			11/26/1996	
	A4	JP	8-245414			09/24/1996	
	A5	JP	9-235276			09/09/1997	
	A6	JP	8-99996			04/16/1996	
	A7	JP	8-50829			09/03/1996	
	A8	WO	96/409966			12/19/1996	
	A9	WO	96/38481	The Board of Regents of the University of Oklahoma	12/05/1996		
	A10	EP	0 811 384	SEIYAKU et al.	12/10/1997		
	A11	WO	99/64069	Ophidian Pharmaceuticals, Inc.	12/16/1999		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A12	POWRIE et al., "Inhibition of Th1 Responses Prevents Inflammatory Bowel Disease In scid Mice Reconstituted With CD45Rbhi CD4+ T Cells", <i>Immunity</i> , Vol. 1:553-562, (1994).	
	A13	TAKAGI et al., "Blockage Of Interleukin-6 Receptor Ameliorates Joint Disease In Murine Collagen-Induced Arthritis", <i>Arthritis Reheumatism</i> , Vol. 41(12):2117-2121, (1998).	
	A14	MITSUYAMA et al., "Soluble Interleukin-6 Receptors In Inflammatory Bowel Disease; Relation To Circulating Interleukin-6", <i>Gut</i> , Vol. 36:45-49, (1995).	
	A15	VAN DULLEMEN et al., "Treatment Of Crohn's Disease With Anti-Tumor Necrosis Factor Chimeric Monoclonal Antibody (cA2)", <i>Gastroenterology</i> , Vol. 109:129-135, (1995).	
	A16	SASAJIMA et al., "Changes in Serum Cytokine Profile During Treatment of Ulcerative Colitis", <i>Journal of Gastroenterology and Hepatology</i> , December 1997, page A274, vol. 12, no. SUPPL., XP-001105732.	

Examiner
Signature

Date
Considered

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not
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⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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<p>Under the Paperwork Reduction Act of 1995, no part of this form is mandatory. It is being used for optional government purposes. It is voluntary to complete it. The public is not required to respond to it, but is free to do so voluntarily. The information will not be mandatory.</p> <p>Substitute for form 1449B/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>Date Submitted: October 3, 2003</p> <p>(use as many sheets as necessary)</p>				Complete if Known	
Sheet	2	of	2	Application Number	Unassigned
				Filing Date	10/03/2003
				First Named Inventor	Hiroaki ITO et al.
				Group Art Unit	1646
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

OTHER PRIOR ART – NON PATENT REFERENCES		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.
	A17	FUNAKOSHI et al., "Spectrum of Cytokine Gene Expression in Intestinal Mucosal Lesions of Crohn's Disease and Ulcerative Colitis", <i>Digestion</i> , January 1998, pages 73-78, vol. 59, no. 1, Basel, China, XP-001064174.
	A18	TATEISHI et al., "Role of Cytokines in Experimental Colitis: Relation to Intestinal Permeability", <i>Digestion</i> , 1997, pages 271-281, vol. 58, no. 3, Basel, China, XP-001095980.
	A19	SEIDMAN et al., "Nutritional Issues in Pediatric inflammatory Bowel Disease", <i>Journal of Pediatric Gastroenterology and Nutrition</i> , 1991, pages 424-438, vol. 12, no. 4, Raven Press, Ltd., New York, XP-001105792.
	A20	ROGLER et al., "Cytokines in Inflammatory Bowel Disease," <i>World J. Surg.</i> Vol. 22, No. 4, April 1998, pp. 382-389.
	A21	KMIEC, "Cytokines in Inflammatory Bowel Disease," <i>Arch. Immunol. Ther. Exp. (Warsz)</i> , Vol. 46, No. 3, 1998, pp. 143-155.
	A22	HOGEZAND et al., "Selective Immunomodulation in Patients With Inflammatory Bowel Disease-Future Therapy or Reality?" <i>Neth. J. Med.</i> February 1996, Vol. 48, No. 2, pp. 64-67.

Examiner Signature	Date Considered	Initials _____ Comments _____
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not used. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO).

Time will vary depending upon the needs of the individual case. Any comments or
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